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Attorneys for Plaintiff State of Oregon

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

STATE OF OREGON; STATE OF NEW YORK; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NORTH CAROLINA; COMMONWEALTH OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WISCONSIN,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as
Secretary of Health and Human Services;

Case No. 6:19-cv-00317-MC

DECLARATION OF JOSEPH L.
ALIFANTE IN SUPPORT OF
STATES' MOTION FOR
PRELIMINARY INJUNCTION

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
DIANE FOLEY, in her official capacity as the
Deputy Assistant Secretary, Office of
Population Affairs; and the OFFICE OF
POPULATION AFFAIRS,

Defendants.

I, Joseph L. Alifante, declare:

1. I am the President and CEO of the New Jersey Family Planning League (“NJFPL”), a 501(c)(3) not for profit organization. NJFPL is currently the statewide NJ grantee for federal Title X family planning services. As the CEO, I am responsible for overseeing all aspects of our Title X project, including overseeing compliance with Title X Statute, regulations and program requirements. I make this declaration from personal knowledge and based on records from the NJFPL.

The Title X Program in New Jersey

2. NJFPL is the sole Title X grantee in New Jersey. For over 44 years, NJFPL has been managing a system of sub-recipient agencies who provide quality family planning services to the residents of New Jersey. NJFPL’s mission is to provide high quality comprehensive family planning and accompanying preventive reproductive health care to every person seeking such services.

3. NJFPL currently provides Title X funding to 10 sub-recipient agencies that operate family planning and reproductive health services at 47 service sites (“Title X clinics”) throughout the 21 counties in New Jersey. Nine counties have only one Title X clinic, while 12 have multiple sites. The sub-recipient agencies include federally qualified health centers (“FQHCs”), Planned Parenthood affiliates, a county health department, a hospital-based agency,

and other community-based non-profit family planning service providers. A list of the sub-recipient agencies and Title X clinics is attached as Exhibit A.

4. In fiscal year 2017-2018, the NJFPL's grant award was \$8.8 million. Other sources of funds include State family planning funds; other federal grants awarded by the New Jersey Department of Health; funds received from patient services revenues (including Medicaid, private insurance and patient self-pay fees); and sub-recipient funds. The integration of funding streams allows the NJFPL Title X project to leverage its grant funding streams with other current and potential resources in order to serve a higher number of low-income patients. Following the restoration of state funding in 2018, NJFPL has been able to expand its service network to recapture patients lost when state funds were eliminated in 2010.

5. In calendar year 2017, our network served approximately 99,800 patients. The diverse network of family planning agencies in NJFPL's service delivery system is a vital component of the state's public health infrastructure for low-income women, teens, and men. It is one of the largest single existing systems for the provision of preventive health care in the state.

NJFPL's Administration of the Title X Project

6. The NJFPL identifies potentially-qualified sub-recipient agencies capable of providing required Title X family planning services using a consistent set of criteria. Each agency is required to submit an application describing the number of patients to be served, details of the services to be provided, qualifications of their project staff, and their funding request as part of a financing plan to support the cost of Title X project operations. Family planning services must be provided in accordance with the Title X statute, legislative mandates and regulations.

Eligibility criteria include:

- Located in geographic areas with high level of need;
- Priority given to services to low-income populations;
- Able to offer all required Title X services on-site or by referral, including a broad range of acceptable and effective family planning methods, including FABMs, and services and which does not include abortion as a method of family planning;
- Medical services are provided under the direction of a physician with special training or experience in family planning;
- Adequate budget/ financing plan supporting project work plan goals, objectives, and activities;
- Strong financial management infrastructure with established policies and procedures to assure the effective and timely use of the Title X grants funds; and
- Commitment to establish and provide services that are consistent with Title X statute, legislative mandates and regulations, including policies that clearly indicate that no Title X funds will be used in programs where abortion is a method of family planning.

7. All NJFPL sub-recipient agencies are required to enter into a contract with the NJFPL. The NJFPL sub-recipient contract indicates that all agencies must make available to all individuals the services provided under the Title X project, including core family planning as described in a sub-recipient's Project Work Plan. These services do not include abortion as a method of family planning. The sub-recipient agency establishes and implements policies and procedures governing personnel, financial, and programmatic management, as specified more fully in 45 C.F.R. Part 75, as applicable. Such policies and procedures must be consistent with NJFPL's Title X Notice of Award as issued by the U.S. Department of Health and Human

Services (“HHS”), including all Special Conditions, Special Terms and Requirements, and Standard Terms.

8. All sub-recipient agencies of the NJFPL are required to provide services in compliance with the Title X statute and regulations, appropriations language, Legislative Mandates, and other applicable laws and standards as described in the Program Requirements for Title X Funded Family Planning Projects. Health centers are required to be licensed through the New Jersey Department of Health and must comply with all applicable state regulations as described in N.J.A.C. Title 8, Chapters 43A and 43E. Professional clinical staff are required to be licensed by their respective professional boards (Medical Examiners, Nursing) and must maintain updated licensure at all times. Clinical services are evidence-informed and are guided by the Centers for Disease Control and Prevention’s publication, *Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs*, and appropriate national standards and practice guidelines.

9. NJFPL staff review regulatory compliance and clinical quality of services through annual health center site reviews. Compliance review is accomplished through agency policy and protocol review, patient chart review, patient visit follow-through, facility licensure and document inspection, financial monitoring, and monthly, semi-annual and annual submission of required data elements. This review utilizes NJFPL’s full program review tool, which is based upon the HHS Office of Population Affairs Title X Program Review Tool.

10. Title X funds do not fund abortion-related services in New Jersey. NJFPL has comprehensive oversight and monitoring procedures that support compliance with Title X abortion separation regulations and practice requirements as outlined in the Title X Statute and Program Regulations. In the Title X application process, NJFPL provides to HHS detailed

budgets and supporting narrative information on NJFPL's financial system and how Title X expenses are kept separate from non-Title X project expenses. Like all Title X grantees, NJFPL undergoes independent audits each year in compliance with federal grant audit requirements. HHS also conducts comprehensive grantee program reviews nationwide that review systems to ensure that the grantees and sub-grantees are not in violation of Title X requirements. In addition, NJFPL monitors for compliance with Title X requirements by conducting annual sub-recipient program and fiscal reviews of each of its sub-recipient agencies. NJFPL's current practices oversee compliance with all current Title X Program requirements, including the separation of all non-Title X services and activities in the project.

Importance of Title X Program as Part of New Jersey's Health System

11. New Jersey's Title X clinics provide a full range of reproductive health services, including counseling and education about achieving or preventing pregnancy, all FDA-approved contraceptive methods, fertility-awareness based methods of family planning, basic infertility services, pregnancy testing and options counseling (including appropriate referrals), preconception care, breast and cervical cancer screening, wellness screening for blood pressure, BMI and other factors, HPV vaccination, testing and treatment for sexually-transmitted diseases, physical exams, screening for intimate partner violence and substance abuse, and referrals for social services, specialty care and/or primary care if not provided on site. In 2017, the Title X project in New Jersey prevented approximately 19,300 unintended pregnancies, 9,100 unplanned births, and 6,500 abortions.¹

¹ Guttmacher Institute, *Health Benefits and Cost Savings of Publicly Funded Family Planning Calculator*, <https://data.guttmacher.org/calculator>.

12. In 2017, approximately 99,800 patients received services at New Jersey's Title X clinics. About 89,900 patients were female, and about 9,900 were male. 36% of patients served had public health insurance such as Medicaid, 16% had private health insurance, and 48% were uninsured. 54% of patients served were under 100% of the federal poverty level (FPL), while 94% were below 200% of the FPL.

13. According to data from the Guttmacher Institute, approximately 1.1 million women in New Jersey are in need of contraceptive services, and approximately 455,300 of these women are in need of publicly subsidized contraceptive services.²

14. New Jersey's Title X clinics serve all patients, regardless of income or insurance status and offer equal services, including a full range of reproductive health and contraceptive services, to all who present for them. When a patient has public or private health insurance, that insurance is billed for services provided. However, when the patient does not have insurance or the services are not covered, services are provided on a sliding fee scale, with no charge for patients with family incomes at or below 100% of the federal poverty level, and incremental charges for those with incomes between 101% and 250% of the federal poverty level.

15. It is the policy and practice of NJFPL's Title X project that neither the cost of services and supplies nor the procedures for collecting fees will present a barrier to receive family planning services or supplies for the client who has been assessed a fee. Further, clients who are assessed a fee may not be denied services because of an inability to pay. Each agency has a sliding fee schedule with the full fee based on the reasonable cost of services and supplies. Charges within sliding fee schedules are based on periodic cost studies. A schedule of discounts is revised annually, reflecting the most recent published federal poverty guidelines. Fees may be

² Guttmacher Institute, *Guttmacher Institute Data Center*, <https://data.guttmacher.org>.

waived for individuals with family incomes above 100% of the federal poverty level who, as determined by the service site project director, are unable, for good cause, to pay for family planning services.

Impact of the Final Rule's Regulatory Changes in New Jersey if Not Enjoined

Issues Related to Physical and Financial Separation of Abortion Services

16. The new physical separation requirements and the accompanying intensification of the financial requirements in the Final Rule will negatively impact numerous project functions.

17. The new physical separation requirements will force healthcare providers that also offer abortion as a non-family planning service, as well as providers that wish to continue to offer patients truly non-directive pregnancy options counseling and referrals, to choose between two problematic options. One choice is to leave the Title X network in order to be able to maintain comprehensive patient-centered care based on national evidence-based standards. This option risks abandoning patients who rely on services and may not have other resources, leaving them without options for receiving family planning services. The other choice is to stay in the Title X network and make drastic programmatic and service changes that curtail available services and depart from medical ethics and widely-accepted standards of care in order to comply with the Final Rule's broad new restrictions. Either scenario limits the availability of quality healthcare to patients in need, who are largely from communities that already experience disproportionate health disparities and high risk of poor health outcomes.

18. In addition, while the Final Rule purports to provide clarification around separation requirements, it does the opposite, creating less clarity and more confusion. As a Title X grantee, the NJFPL will be faced with the difficult, if not impossible, task of determining

which activities might possibly be seen under the Final Rule as “encourag[ing],” “promot[ing],” or “advocat[ing]” for abortion, and thus trigger the separation requirements.

19. For example, NJFPL maintains membership with and/or subscribes to publications from organizations whose work directly or indirectly supports our Title X project through research, establishment of clinical care standards, provision of training and professional development opportunities, support for healthcare quality standards, and facilitation of connections with colleagues, stakeholders, community and faith-based organizations. Some of these organizations may also do research, provide information, or discuss issues related to aspects of women’s health beyond family planning, such as abortion. It may be impossible to know what percent of the work of any one organization involves abortion as a subject, or at which activities or events this will be a substantial agenda item, and whether this work will be seen as encouraging, promoting, advocating or supporting abortion. The requirements of separation could complicate NFPL and sub-recipient’s membership, subscription, and/or participation with these organizations and forums.

20. The NJFPL and sub-recipient agencies also collaborate with organizations that serve similar communities, including healthcare providers, social services, community and faith-based organizations, strengthening our ability to meet the needs of our patients. These relationships are critical to developing a substantial referral network with a wide range of providers to meet the needs of our patients, for establishing a presence in the community to reach patients in need of care, and to raise awareness about the value and importance of family planning. NJFPL cannot be in full control of the messaging that comes from other providers and organizations, and the Final Rule would create confusion and fear about which community partnerships can be maintained. The broadened separation standards imposed by the Final Rule

will require intensified procedures in order to comply and are likely to preclude accessing information from and partnering with other organizations. The loss of these relationships would directly impact patients' access to services and our ability to meet the full range of needs presented by our patients.

21. The impact of trying to comply with increased and unclear standards for separation requirements is likely to create a chilling effect on providers. Some agencies may be unwilling or unable to comply, and may cease to participate in the Title X project, possibly resulting in clinic closures. Moreover, standards are so unclear that agencies and providers seeking to comply may be forced to protect themselves by taking unnecessarily extreme measures. Agencies that remain in the Title X project will end up forgoing otherwise permitted activities because they do not know where the line is and want to stay safely in the project, reducing patients' access to valuable resources and services.

Issues Related to Contraceptive Services

22. Providing access to the full range of contraceptive methods and appropriate patient-centered counseling in order to assist women and men in preventing or achieving a pregnancy has long been central to the mission of NJFPL as a Title X grantee. The NJFPL and its sub-recipients utilize practice standards presented within *Providing Quality Family Planning Services, Recommendations of the CDC and US Office of Population Affairs*, supported by other current nationally recognized standards of care and guidelines (such as those of the American College of Obstetricians and Gynecologists, the Centers for Disease Control and Prevention, the US Preventative Screening Task Force, the American Academy of Pediatrics, and the American Society for Reproductive Medicine).

23. All NJFPL sub-recipients provide a full range of FDA-approved and effective contraceptive methods including hormonal methods, as well as fertility-awareness based methods, preconception care, and basic infertility services. Staff are trained to provide patient-centered, non-directive counseling in a supportive, non-judgmental manner, and patients are provided factual information on the effectiveness, advantages, risks and side effects of the contraceptive methods. The patient has the opportunity to ask questions and is supported in selecting the method that is right for them based on the patient's reproductive life plan, health factors and other needs. In most cases patients can receive their chosen method at that visit. If it is necessary for a patient to return at a later time for the selected method, an interim contraceptive is offered or a plan for avoiding pregnancy is developed. All patients are counseled on the importance of using condoms to protect against the transmission of sexually transmitted diseases ("STDs") and HIV. Teens are counseled regarding the value of sexual-risk avoidance and delaying the onset of sexual activity. The combination of and ready access to all of these services work together to achieve the public health goals of reduced unintended pregnancies and improved outcomes births and maternal and infant health.

24. Removal of evidence-based and currently accepted practice standards, including removal of the term "medically approved," and the lack of specificity about on-site provision of a broad range of FDA approved contraceptive methods is contrary to best practices employed in the Title X project. The expansion of the definition of family planning services in the Final Rule would not necessitate the provision of full comprehensive family planning and contraceptive services. It severely weakens the Title X service network by equating providers that offer a few limited services with comprehensive providers whose practices are aligned with nationally recognized standards of care. Limited service providers will have dramatically fewer costs but

leave patients with unmet needs and potentially missed diagnoses—some of which will end up falling on other more comprehensive Title X providers to address. In addition, truly comprehensive family planning medical care providers will be competing for Title X funds with the limited service providers, agencies that have significantly fewer costs and appear more efficient as a result. If comprehensive family planning medical providers have funding reduced because Title X funds are spread out to include projects which only provide one family planning method or a very limited scope of family planning services, patients' access to comprehensive services will be reduced and unmet needs will increase.

Issues Related to Pregnancy Counseling

25. In accordance with Title X's legislative requirements, NJFPL's sub-recipients all provide non-directive pregnancy options counseling that puts the patient's own stated needs, reproductive choices, and requests at the heart of the pregnancy counseling and the referrals that are provided. The prohibition on abortion referral in the Final Rule and the requirement to refer pregnant patients to a health care provider for prenatal health care, by contrast, will require providers to disregard the patient's own wishes and interests. Not only is this contrary to the statutory requirements of Title X as NJFPL understands them, it is also contrary to medical ethics and the practice recommendations of the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, and the American Academy of Pediatrics.

26. Similarly, the requirement that, when a patient states that she has decided to terminate her pregnancy, Title X providers can only share a list of "licensed, qualified, comprehensive primary health care providers (including providers of prenatal care)," some of whom may or may not provide abortion services, and cannot explain the specific care a patient

would receive from those providers, ties Title X providers' hands and requires them to withhold accurate medical information in a way that is contrary to medical ethics and would undermine trust in the provider and the Title X system.

27. As a result of these pregnancy counseling requirements, medical directors and providers at many Title X clinics will face ethical conflicts, as they will be directed to provide care contrary to evidenced based standards of care that have been established and embraced to appropriately meet patient-centered needs and services. As a result, some directors and providers may choose to leave Title X clinics, reducing access to services and quality of care for patients.

28. In addition, at Title X clinics in New Jersey, while medical health services are provided by physicians and advanced practice providers, the majority of counseling is provided by registered nurses, social workers, licensed practical nurses, and highly trained reproductive health counselors and health educators. Additionally, Title X clinics see a large number of walk-in pregnancy test patients, most of whom receive a very limited scope of services at that visit. Therefore, even to the extent that the Final Rule allows what the Final Rule calls "nondirective" abortion counseling by *physicians and advanced practice providers* in some circumstances, in practice it is not feasible for every patient with a positive pregnancy test to be seen by a physician or an advanced practice provider at our Title X clinics while still maintaining efficient clinic flow and continuing to serve current numbers of patients of all kinds.

Overall Impacts of the Final Rule

29. In sum, the Final Rule will cause confusion and disruption, and NJFPL and its providers will find it extremely difficult and burdensome to comply with the new requirements. If the Final Rule goes into effect, the NJFPL Title X project and all sub-recipient agencies will

have to come into compliance with all requirements by May 3, 2019; except for the financial separation requirements and physical separations requirements, which must be complied with by July 2, 2019, and March 4, 2020, respectively. In order to come into compliance, NJFPL will need to amend Title X program requirements, administrative policies and procedures, and grantee standards with clinical protocols. The NJFPL will also have to provide education and training on the content of the Final Rule, including changes to clinical practice related to pregnancy options counseling. Participating Title X clinics will also need to revise all project materials (brochures, referral information, patient information) related to pregnancy non-directive options counseling services. The NJFPL could theoretically continue to seek Title X funding if the Final Rule goes into effect, but the cost of compliance would be dramatic and possibly prohibitive, both for NJFPL and for its sub-recipient agencies.

30. NJFPL believes that it will be difficult to retain or attract agencies willing to comply with the Final Rule. In addition to being affected by the potentially prohibitive costs of compliance, most providers will be opposed to the problematic and unethical changes in the Final Rule that run counter to high quality, patient-centered, evidenced based care that currently exists in the Title X project. As a result of these issues, some current sub-recipient agencies may be unable or unwilling to continue to participate in the Title X project, and NJFPL believes it would find it difficult to find qualified agencies willing and able to comply with the Final Rule. For agencies who remain in the Title X project, complying with the Final Rule will result in being unable to provide the same full range of high quality family planning and reproductive health services.

31. Title X funded providers are a critical part of the health care safety net in the communities they serve. Patients who are unable to continue to receive family planning services

at a Title X clinic will need to seek services elsewhere (a barrier to care). Depending on the community, other family planning providers may not be accessible due to distance, cost, language barriers, confidentiality concerns, or quality and comprehensiveness of services available. Although FQHCs exist in all NJ counties, they are not equipped to absorb the impact of the loss of family planning service providers in their communities – whether that loss is due to ineligibility for Title X funds or due to disbursement of funds more widely to include providers that do not truly offer the full range of family planning services and methods. Fewer providers means increased wait times (for appointments and in waiting rooms), leading to delayed care and increased opportunity for unintended pregnancy, HIV and STDs to go undetected and/or untreated, and for other health issues (such as cancer detection, diabetes or other risk factors for a potential pregnancy) to go unaddressed and result in worsened outcomes. Many FQHCs are already struggling to meet the demand for care in the populations and communities they serve. Lack of family planning services oversight or a compromise to the standards Title X currently provides will impact the quality of services available to those seeking sexual and reproductive health care and increase the risk for unintended pregnancies and other poor health outcomes. A 2018 study³ confirmed that non-Title X FQHCs often fall short of meeting established family planning best practices and guidelines:

Title X-funded sites consistently show a larger range of onsite contraceptive methods across all types of methods, including natural family planning instruction and emergency contraception. Title X-funded health center sites are substantially more likely – 48 percent compared to 15 percent of sites not receiving Title X funding – to offer all seven of the most effective methods onsite. Title X-funded sites also consistently show greater incorporation of evidence-based best practice methods, including prescribing oral contraceptives without requiring a pelvic

³ Wood, S., Strasser, J., Sharac, J., Wylie, J., Tran, T-C., Rosenbaum, S., Rosenzweig, C., Sobel, L., Salganicoff, A., *Community Health Centers and Family Planning in an Era of Policy Uncertainty* (2018), available at <http://files.kff.org/attachment/Report-Community-Health-Centers-and-Family-Planning-in-an-Era-of-Policy-Uncertainty> (last accessed Feb. 19, 2019).

exam and use of the “quick start” method for oral contraception that ensures that women who seek it have more rapid access to effective contraception.

Moreover, the study stated, “health centers reported limited capacity to accept new patients; 51 percent reported that they could increase patient capacity but only between 10 and 24 percent; only 6 percent reported that they could absorb a 50 percent or greater patient increase.”

32. In addition to providing critical family planning services, four of the 10 sub-recipient agencies in the NJFPL’s Title X project, including all the FQHCs, offer a full range of primary care services, while the other six agencies provide referrals for primary care services as needed. A loss of providers in the NJFPL’s Title X project service network would therefore not only affect reproductive health care services in New Jersey, but would also affect access to health care more broadly in the communities served by those providers.

I declare under penalty of perjury that the foregoing is true and correct.

DATED March 19, 2019.

A handwritten signature in dark ink, appearing to read "Joseph L. Alifante", is written over a horizontal line.

Joseph L. Alifante
President and CEO
New Jersey Family Planning League

Exhibit A

New Jersey Family Planning League Title X Project Sub-Recipient Agencies & Clinic Sites

Sub-recipient Agency	Clinic Site	County
Alliance Community Health Center	Jersey City (Bergen Ave.)	Hudson
	Jersey City (Christopher Columbus Dr.)	Hudson
Cape May County Health Department	Cape May Court House	Cape May
DAYAM (Division of Adolescent & Young Adult Medicine)	Newark	Essex
FamCare	Bridgeton	Cumberland
	Glassboro	Gloucester
	Glassboro (Rowan University)	Gloucester
	Pennsville	Salem
	Vineland	Cumberland
Family Planning Center of Ocean County	Lakewood	Ocean
Hoboken Family Planning	Hoboken	Hudson
	Union City	Hudson
	West New York	Hudson
North Hudson Community Action Corporation	Englewood	Bergen
	Garfield	Bergen
	Hackensack	Bergen
	Harrison	Hudson
	Jersey City	Hudson
	North Bergen	Hudson
	Passaic	Passaic

Exhibit A

New Jersey Family Planning League Title X Project Sub-Recipient Agencies & Clinic Sites

	Union City	Hudson
	West New York	Hudson
Planned Parenthood of Northern, Central, & Southern NJ	Bellmawr	Camden
	Camden	Camden
	Delran	Burlington
	Elizabeth	Union
	Englewood	Bergen
	Flemington	Hunterdon
	Freehold	Monmouth
	Hackensack	Bergen
	Hamilton	Mercer
	Morristown	Morris
	New Brunswick	Middlesex
	Newton	Sussex
	Perth Amboy	Middlesex
	Shrewsbury	Monmouth
	Pomona, Galloway Twp.	Atlantic
	Trenton	Mercer
	Washington	Warren
Planned Parenthood of Metropolitan NJ	East Orange	Essex
	Montclair	Essex
	Newark (Ironbound)	Essex
	Newark (Mulberry)	Essex

Exhibit A

New Jersey Family Planning League Title X Project Sub-Recipient Agencies & Clinic Sites

	Paterson	Passaic
Zufall Health Center	Dover	Morris
	Hackettstown	Warren
	Somerville	Somerset